

# **EXHIBIT 19**



## Urology at UCLA

### Mesh Related Complications

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Phone: (310) 794-7700

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UCLA Urology has become a referral center for patients who have suffered from mesh related complications due to vaginal and sling mesh. To date, we have performed over 400 mesh complication surgeries. Mesh complications are highly complex issues and each individual is treated according to their unique problem. If you are suffering from a mesh-related issue, we may be able to help you.

#### What to expect at your evaluation?

In addition to a detailed history and genitourinary-focused examination, your evaluation may include a translabial ultrasound, urodynamics, and cystoscopy. Not all of these additional procedures are always necessary. The translabial ultrasound allows us to visualize the mesh and its placement and position in the vaginal area. A cystoscopy, where a scope with a camera at the end is used to evaluate the urinary tract, may be performed. In addition, if incontinence is present, urodynamics may be performed.

[Learn more about urodynamics studies »](#)

If you are suffering from a complication of transvaginal mesh and want to learn more >> [Link to any of our publications.](#)

[Learn more about mesh \(PDF\) »](#)

#### Surgical Mesh Implants for Pelvic Organ Prolapse

Surgical mesh is a medical device that is used to provide additional support when repairing weakened or damaged tissue. The majority of surgical mesh devices currently available for use are made from man-made (synthetic) materials or animal tissue.

Surgical mesh made of synthetic materials can be found in knitted mesh or non-knitted sheet forms. The synthetic materials used can be either absorbable, non-absorbable, or a combination of absorbable and non-absorbable materials.

Animal-derived mesh are made of animal tissue, such as intestine or skin, that have been processed and disinfected to be suitable for use as an implanted device. These animal-derived mesh are absorbable. The majority of tissue used to produce these mesh implants are from a pig (porcine) or cow (bovine).

Non-absorbable mesh will remain in the body indefinitely and is considered a permanent implant. It is used to provide permanent reinforcement in strength to the urogynecologic repair. Absorbable mesh will degrade and lose strength over time. It is not intended to provide long-term reinforcement to the repair site. As the material degrades, new tissue growth is intended to provide strength to the repair.

Surgical mesh can be used for urogynecologic procedures, including repair of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). It is permanently implanted to reinforce the weakened vaginal wall for POP repair or support the urethra or bladder neck for the repair of SUI. There are three main surgical procedures performed to treat pelvic floor disorders with surgical mesh:

- Transvaginal mesh to treat POP
- Transabdominal mesh to treat POP
- Mesh sling to treat SUI

Each of these procedures has unique risks and benefits and it is important not to confuse the procedures and the risks and benefits.

The FDA identified serious complications associated with the use of urogynecologic surgical mesh.

[Learn more about mesh-related concerns »](http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm) (<http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm>)

#### Concerns about Surgical Mesh for POP

Based on an updated analysis of adverse events reported to the FDA and complications described in recent scientific literature, on July 13, 2011 an [FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse](#) (<http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm262435.htm>) was issued to inform the medical community and patients that:

1. serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**; and
2. it is not clear that **transvaginal** POP repair with mesh is more effective than traditional non-mesh repair

#### Mesh for Transabdominal Repair of POP

Mesenteric Complications Pelvic Medicine and Reconstructive Surgery

Surgical mesh has been used for over 15 years for transabdominal procedures including sacrocolpopexy (transabdominal, robotic or laparoscopic) and uterine suspension with good results and minimal complications. Although mesh complications include vaginal extrusion, erosions or infection, these complications are rare and the excellent overall outcomes, durability and patient satisfaction warrant their use. The FDA had not found evidence of major complications from the use of mesh in these transabdominal surgeries.